

AMENDMENTS TO THE CLAIMS

1. (Original) Process for the synthesis of isobutyl methyl 1,4-dihydro-2,6-dimethyl-4-(2-nitrophenyl)-3,5-pyridine dicarboxylate (Nisoldipine) based on the reaction of isobutyl 2-(2-nitrobenzylidene)acetoacetate with methyl 3-aminocrotonate, added to the reaction mixture at a time or portionwise, in non-polar solvent, to give crude Nisoldipine.
2. (Original) The process as claimed in claim 1, wherein the non-polar solvent is selected from the group consisting of aliphatic or cycloaliphatic solvents.
3. (Original) The process as claimed in claim 2, wherein the solvent is selected from the group consisting of cyclohexane and/or n-hexane.
4. (Original) The process as claimed in claim 1, wherein the reaction of isobutyl 2-(2-nitrobenzylidene)acetoacetate and methyl 3-aminocrotonate is carried out in the presence of 4-dimethylaminopyridine.
5. (Original) The process as claimed in claim 1, wherein, downstream of the reaction of isobutyl 2-(2-nitrobenzylidene)acetoacetate with methyl 3-aminocrotonate in a non-polar solvent to give crude Nisoldipine, said Nisoldipine is purified by crystallisation from a water/water soluble solvent mixture to give a pure Nisoldipine final product.
6. (Original) The process as claimed in claim 5, wherein the water/water soluble solvent mixture is acetone/water.

7. (Original) The process as claimed in claim 1, wherein, upstream of the reaction of isobutyl 2-(2-nitrobenzylidene)acetoacetate with methyl 3-aminocrotonate, said Nisoldipine synthesis intermediate, i.e. isobutyl 2-(2-nitrobenzylidene)acetoacetate, is obtained by causing 2-nitrobenzaldehyde to react with isobutyl acetoacetate in methylene chloride, as solvent, in the presence of a catalytic amount of piperidine formate at a temperature of -10°C to 50°C.

8. (Original) The process as claimed in claim 7, wherein the reaction of 2-nitrobenzaldehyde with isobutyl acetoacetate is carried out at a temperature of 20°-50°C.

9. (Original) The process as claimed in claim 8, wherein the temperature ranges from 27° to 33°C.

10. (Original) The process as claimed in claim 7, wherein the catalyst, piperidine formate, forms in situ in the reaction mixture by addition of equimolar amounts of formic acid and piperidine.

11. (Original) The process as claimed in claim 7, wherein the amount of catalyst, piperidine formate, used is 0.05-0.7 mol catalyst/mol 2-nitrobenzaldehyde.

12. (Original) The process as claimed in claim 11, wherein the amount of catalyst is 0.05-0.6 mol catalyst/mol 2-nitrobenzaldehyde.

13. (Original) The process as claimed in claim 12, wherein the amount of catalyst is 0.25 mol catalyst/mol 2-nitrobenzaldehyde.

14. (Original) The process as claimed in claim 7, wherein isobutyl 2-(2-nitrobenzylidene)acetoacetate is isolated in the presence of aqueous acetic acid as solvent.

Claims 15-22 (Canceled)